UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,350	12/18/2001	Michael N. Pollak	28758.57	4785

7590 12/19/2006

Diagnostic Systems Loboatories Inc.
Attn In House counsel
445 Medical Center Boulvard
Webester, TX 77598

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,350	POLLAK ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2006 has been entered.

2. Claims 21-27 are pending and examined on the merits.

Claim Rejections Withdrawn:

3. The rejection of claims 21-27 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of predicting a doubling of risk for prostate cancer for every 100 ng/ml increase in IGF-I levels, does not reasonably provide enablement for the full scope of the claimed methods, wherein any concentration above a reference level is deemed to indicate an increased risk for prostate cancer is withdrawn upon further consideration.

4. The rejection of claims 21-27 under 35 U.S.C. 102(a) as being anticipated by Mantzoros (Mantzoros et al, British Journal of Cancer 76(9): 1115-1118, 1997) is withdrawn in view of the amendments to the claims wherein the methods comprise comparing the IGF-I level of a healthy individual to that of a reference group.

New Grounds of Rejection:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated either by Juul-A (Juul, A. et al. J. Clin. Endocrinol. Metab., 78(3): 744-752, 1994) or by Juul-B (Juul, A. et al., Clinical Endocrinology, 41: 85-93, 1994; cited in IDS).

Claims 21-27 are drawn to methods that comprise the active steps of measuring IGF-I levels in individuals in a reference group and in healthy individuals that are not in the reference group and then comparing the levels of IGF-I obtained from the two measurements. The intended use of the claimed methods is for the prediction of risk of a healthy individual later developing prostate cancer. The claims do not describe the characteristics of the "healthy individuals" other than to indicate that these individuals do not have prostate cancer. Because the claims do not specify characteristics of the individuals of the reference group other than that the individuals do not have prostate cancer, the claims are interpreted broadly as reading on methods where IGF-I levels are measured in at least two individuals that do not have prostate cancer and that a comparison of IGF-I levels is made.

Juul-A measures serum, plasma and whole blood total IGF-I in healthy individuals and compares IGF-I levels found in different groups of healthy individuals (see page 745, 1st to 2nd column). For example, on page 747 males and females are compared (see Figure 2). Also,

serum IGF-I levels from differently aged adults are compared (see Figure 3). Juul-A also demonstrates how to compare a hypothetical IGF-I serum concentration of a 13 year old boy to reference values derived from measuring IGF-I levels in groups of healthy boys (see page 751, 1st to 2nd column). Therefore, Juul-A teaches methods that are the same as that claimed, because Juul-A teaches methods with the same active steps as those in the claimed methods .

Juul-B measures serum IGF-I levels in individuals that do not have prostate cancer (see page 86, 1st column). Juul-B measures serum IGF-I levels in individuals with a growth hormone (GH) level that is less than 2mIU/l and compares serum IGF-I levels in individuals with higher GH levels (2-10mIU/l and greater than 10mIU/l; see Table 1, page 88). Therefore, Juul-B measures IGF-I levels in groups of individuals without prostate cancer and compares these levels to other individuals without prostate cancer. Thus, Juul-B teaches a method that is the same as that claimed, because Juul-B teaches methods using the same active steps as those recited in the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
December 10, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER